ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN- isopropyl alcohol liquid Home Smart Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

HEALTH SMART ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN

Active ingredient (by volume)

Isopropyl alcohol (50% concentrate)

Purpose

topical antimicrobial

Uses

- to decrease germs in minor cuts and scrapes
- helps relieve minor muscular aches due to exertion

Warnings

For external use only

- flammable, keep away from fire and flame
- will produce serious gastric disturbances if taken internally

Ask a doctor before use if you have deep puncture wounds or serious burns

When using this product

- do not get into eyes or mucous membranes
- use only in a well-ventilated area

Stop use and ask a doctor if condition persists or gets worse

Keep out of reach of children.

In case of an accidental ingestion, contact a Poison Control Center immediately

Directions

- apply to skin directly of with clean gauze, cotton or swab
- for rubbing apply liberally and rub with hands

Other information

- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- keep bottle tightly closed

Inactive ingredient

Water, methyl salicylate, laneth-75, FD&C Blue #1, FD&C Yellow #5

PRINCIPAL DISPLAY PANEL

HEALTH SMART ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN

TOPICAL ANTIMICROBIAL 12 FL.OZ (354 mL)

HEALTH SMART 50% ISOPROPYL RUBBING ALCOHOL WITH WINTERGREEN OIL
Drug Facts
Active Ingrdient (by volume) Purpose Isopropyl alcohol (50% concentrate)topical antimicrobial
Uses • to decrease germs in minor cuts and scrapes • helps relieve minor muscular aches due to exertion
Warnings • For external use only • flammable, keep away from fire and flame • will produce serious gastric disturbances if taken internally
Ask a doctor before use if you have deep puncture wounds or serious burns
When using this product • do not get into eyes or mucous membranes • use only in a well-ventilated area
Stop use and ask a doctor if condition persists or gets worse.
Keep out of reach of children. In case of an accidental ingestion, contact a Poison Control Center immediately.
Directions • apply to skin directly of with clean gauze, cotton or



ISOPROPYL RUBBING ALCOHOL 50% WITH WINTERGREEN

isopropyl alcohol liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:52862-023	
Route of Administration	TOPICAL				
Active Ingredient/Active	e Moiety				
Indredient Name			Basis o Strengt		Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL		50 mL in 100 mL
Inactive Ingredients					
	Ingredient Name			S	strength
WATER (UNII: 059QF0KO0R)					
METHYL SALICYLATE (UNII: LAV	5U5022Y)				
PEG-75 LANOLIN (UNII: 091790)	(7TB)				
FD&C BLUE NO. 1 (UNII: H3R47)	(3TBD)				

Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:52862- 023-03	119 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
2	NDC:52862- 023-04	178 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
3	NDC:52862- 023-06	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
4	NDC:52862- 023-09	295 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
5	NDC:52862- 023-10	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
6	NDC:52862- 023-11	414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
7	NDC:52862- 023-12	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/18/2020		
Marketing Information					
	Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/18/2020	

Labeler - Home Smart Products (161872676)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52862-023)

Revised: 1/2022

Home Smart Products